PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 664981	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2005/003621	International filing date *(day/month/year)* 03 March 2005 (03.03.2005)	Priority date *(day/month/year)* 04 March 2004 (04.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 29 November 2006 (29.11.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 664981	Date of mailing *(day/month/year)* FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/003621	03.03.2005	04.03.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant
TAKEDA PHARMACEUTICAL COMPANY LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/003621

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/003621

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-24	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-24	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO

2. Citations and explanations:

<Documents cited in the ISR>
Document 1: JP, 6-157915, A (Warner-Lambert Kabushiki Kaisha), 07 June, 1994 (07.06.94)
Document 2: JP, 6-72862, A (Nippon Elanco Co., Ltd.), 15 March, 1994 (15.03.94)
Document 3: JP, 3-80930, A (Nippon Elanco Co., Ltd.), 05 April, 1991 (05.04.91)
Document 4: JP, 2003-313125, A (CAPSUGEL JAPAN INC.), 06 November, 2003 (06.11.03)
Document 5: JP, 2003-313120, A (Fancl Corp.), 06 November, 2003 (06.11.03)
Document 6: WO, 2002-088246, A1 (Hayashibara Biochemical Labs., Inc.), 07 November, 2002 (07.11.02)
Document 7: JP, 2003-505565, A (Warner-Lambert Co.), 12 February, 2003 (12.02.03)
Document 8: JP, 2000-202003, A (Shionogi Qualicaps Co., Ltd.), 25 July, 2000 (25.07.00)
Document 9: JP, 5-65222, A (Fuji Capsule Co., Ltd.), 19 March, 1993 (19.03.93)
Document 10: WO, 2003-032953, A1 (Takeda Chemical Industries, Ltd.), 24 April, 2003 (24.04.03)
Document 11: JP, 2000-514051, A (Klinge Pharma GmbH), 24 October, 2000 (24.10.00)
Document 12: JP, 2000-212085, A (Nanko Kagaku Seiyaku Kofun Yugen Koshi), 02 August, 2000 (02.08.00)
Document 13: JP, 2003-520225, A (Carlsbad Technology, Inc.), 02 July, 2003 (02.07.03)

<Description>
The subject matters of claims 1-24 do not appear to involve an inventive step in view of documents 1-13 cited in the ISR.

Documents 1-3 describe a hard film composition for capsules, containing gelatin as a main component and mixed with a polyethylene glycol. It is described (1) that even if filling with a hygroscopic medicinal agent is performed and the water content of a capsule film is reduced, the composition does not become brittle, and cracks, chips or the like are scarcely generated in the capsule, which can prevent the contained medicinal agent from leakage caused by the breakage of the capsule, and (2) that even if filling with special contents is performed, there is no delay of temporal disintegration, enough mechanical strength is provided, and disadvantages such as cracks rarely occur.

Documents 4-9 describe a capsule agent whose capsule base material is pullulan. It is described that the capsule agent is stable to discoloration with time and humidity change, has stable mechanical properties and stable solubility, and has an action such as inhibiting the generation of odor and oxidation of components with which the capsule agent is filled.

Furthermore, documents 10-13 describe that a proton pump inhibitor such as a lansoprazole and omeprazole is granulated and a capsule agent is filled with it.

And in pharmaceutical preparations, it is generally practiced that a person skilled in the art selects and decides, as required, the kind of drugs with which a capsule agent is filled, a particular dosage form of a preparation and the like according to the purpose. It is considered that a person

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

skilled in the art could have easily arrived at the subject matters of claims 1-24 by making a drug unstable to water and a drug such as a proton pump inhibitor described in documents 10-13, a preparation in which a capsule containing gelatin as a main component and mixed with polyethylene glycol is filled with the drug, a preparation in which a capsule containing pullulan as a main component is filled with the drug, and further selecting and deciding, as required, a dosage form of a capsule agent with filler.